

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 1 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**RESPONSE TO PLAINTIFFS’ MOTION TO EXCLUDE, OR IN THE ALTERNATIVE,  
TO LIMIT THE OPINIONS AND TESTIMONY OF ROGER MCLENDON, M.D.**

Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”), submit this response (“Response”) to *Plaintiffs’ Memorandum of Law in Support of their Daubert Motion to Exclude, or in the Alternative, to Limit the Opinions and Testimony of Roger McLendon, M.D.* [Doc. # 2011 (the “Memorandum”)]. The cases to which this Response applies are identified in Ex. A.

In their Memorandum, Plaintiffs offer no challenge to any particular opinion offered by Dr. McLendon, nor his qualifications to offer any particular opinion. Rather, they argue that Dr. McLendon should not be permitted to offer *any* opinions in this case because: (1) his quarter-century of neuropathology experience is not specific to the TVT device or mesh Memorandum at 3, (2) his 300+ published articles are not specific to the TVT device or mesh in the human body, *id.* at 4–5, and (3) his Report is primarily a criticism of Dr. Iakovlev’s methodology *id.* at 6. These are not bases to exclude Dr. McLendon’s testimony.

## BACKGROUND

Plaintiffs' Memorandum to strike Dr. McLendon is yet another "Through the Looking Glass" filing by the Plaintiffs regarding expert testimony by a pathologist in these cases. The bottom line: Plaintiffs seek to offer neuropathology testimony from Dr. Iakovlev who has no training in neuropathology, yet simultaneously try to prevent an actual neuropathologist, Dr. McLendon, from explaining to the jury the flaws in Dr. Iakovlev's methodology. For obvious reasons, the Motion should be denied.

### **A. Dr. Iakovlev has no training in neuropathology.**

As this Court is aware, Dr. Iakovlev has no specialized training in neuropathology and never completed a neuropathology fellowship. *See* Ex. B, Expert Report of Dr. Iakovlev, at Exhibit A (Dr. Iakovlev's *curriculum vitae*). Dr. Iakovlev is not board certified in neuropathology. *See id.*; Ex. C, Iakovlev 9/11/15 Dep. Tr. ("Iakovlev *Mullins* Dep.") 10:19–23. Dr. Iakovlev does not specialize in neuropathology. *Id.* at 10:15–18. Dr. Iakovlev did not consult a neuropathologist to determine how to conduct his analysis in pelvic mesh cases. *Id.* at 17:23–18:6. Dr. Iakovlev's only consultation with neuropathologists in pelvic mesh cases was early in his research for these cases and limited to "a few questions" regarding which stains to use to identify nerves in a pathology slide. *Id.* at 15:11–18.

As a result of his lack of training in neuropathology, Dr. Iakovlev does not know the density of pain receptors in the anterior vaginal wall. Ex. D, Iakovlev 11/5/15 Dep. Tr. ("Iakovlev *Carlino* Dep.") 151:17–23. Dr. Iakovlev cannot distinguish between peripheral and autonomous nerves in his slides. *Id.* at 159:19–160:5. He mistakenly believes that autonomous nerves can conduct pain signals, too. Dr. Iakovlev uses stains that are incapable of identifying nerve receptors and photographs nerve twigs at magnifications that are so low they are incapable of identifying nerve receptors. Ex. C, Iakovlev *Mullins* Dep. Tr. 162:6–25; Pls.' Motion Ex. C,

McLendon 9/29/15 Dep. Tr. (“McLendon Dep.”) 49:8–16, 53:8–54:1, 83:19–84:24.

**B. In contrast, Dr. McLendon is an actual neuropathologist.**

Dr. McLendon is board certified in the specialties of Anatomic Pathology and Neuropathology, having trained at Duke University Hospital from 1983 through 1987. *See* Pls.’ Motion Ex. B, Expert Report of Dr. McLendon at 1.

Dr. McLendon has been a faculty member at Duke University Hospital since January 1992, where he has focused his work in surgical and autopsy neuropathology. *See id.* at 1.

He has been a member of the American Board of Pathology Neuropathology Test Development and Advisory Committee since 1998 and is on the editorial boards of the Journal of Neuropathology and Experimental Neurology, Neuropathology and Applied Neurobiology, Archives of Pathology and Laboratory Medicine (where he serves as Sectional Editor), Clinical Neuropathology and Neuro-oncology. *See id.* at 1. In other words, Dr. McLendon helps write the tests that Dr. Iakovlev has never taken.

Dr. McLendon’s opinions in this litigation are based on his extensive knowledge, skill, experience, training, and education relating to the anatomy and pathology of nerves in the peripheral nervous system.

**C. Dr. McLendon’s opinions in this case.**

Dr. McLendon’s expert report in this case analyzes the fundamental scientific principles relating to (1) the physiology and anatomy of nerves; (2) the proper technique to accurately examine and identify nerves in tissue samples, including the appropriate stains and magnification required; (3) the relationship between types of nerves (*i.e.* sensory or autonomic) in the peripheral nervous system and their ability to transmit pain signals to the human brain; (4) the relationship between inflammation and the transmission of pain signals to the human brain; (5) normal innervation of scar tissue, which includes the presence of nerve twigs but the absence of larger

nerves; (6) the literature that addresses pain in transvaginal meshes; and (7) Dr. Iakovelev's numerous failures to abide by the scientific method (*i.e.* failing to test a control group, inconsistency with medical literature, and failure to test and verify his speculative hypotheses). *See* Pls.' Motion Ex. B, Expert Report of Dr. McLendon at 2–10. Dr. McLendon's report also provides his analysis and critique of the tissue sample images provided in Dr. Iakovlev's report, from the perspective of an experienced Anatomic Pathologist and Neuropathologist. *Id.* at 5–10.

## **ARGUMENT**

### **I. Legal Standard**

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at \*\*1–3 (S.D.W. Va. July 8, 2014).

### **II. Dr. McLendon is qualified to offer his opinions in this case.**

Plaintiffs first argue that Dr. McLendon's testimony should be excluded in its entirety because he does not have prior experience in researching or developing polypropylene or mesh. Memorandum at 3–4. This argument ignores the purpose for which Dr. McLendon is being offered in this case.

Dr. McLendon is board certified in both anatomic pathology and neuropathology. *See* Pls.' Motion Ex. C, McLendon 9/29/15 Dep. Tr. 8:3–6. As Dr. McLendon explains, neuropathology is “the study of the brain, the spinal cord, its nerves, the coverings of these tissues as well as their end targets.” *Id.* at 8:13–15; *see also* 33 Am. Jur. Trials 467 §§ 16, 18 (1986) (defining anatomic pathology as “that specialty area of pathology that deals with the diagnosis of disease based on the gross and microscopic examination of tissue samples” and neuropathology as “the pathology of nervous system disorders”).

Plaintiffs' expert pathologist, Dr. Vladimir Iakovlev, has offered opinions directly within the specialized area of neuropathology. For instance, Dr. Iakovlev opines:

- "The tissue is subject to regular mechanisms of pain, out of which there are two main mechanisms for pain: direct irritation of nerve branches and irritation of receptors they supply." Ex. E, Iakovlev 1/29/16 Expert Report at 11.
- "Direct irritation of nerve branches can occur due to nerve entrapment with scar tissue within or encapsulating the mesh." *Id.*
- "The nerves can also become distorted while growing through the mesh and can form traumatic neuroma, a tumor like nerve enlargements known for its painful nature." *Id.*
- "The entrapped and distorted nerves are also at risk for additional pulling, compression and distortion forces due to the earlier described mesh-scar contraction and non-physiological attachments to the surrounding mobile tissues. Nerve involvement has been reported and exceeds 60% for meshes excised for reasons of pain." *Id.*

Dr. Iakovlev does not understand that these opinions lie squarely in the field of neuropathology, seemingly confusing neurology with neuropathology. *See* Ex. C, Iakovlev *Mullins* Dep. Tr. 10:4–19 ("Neuropathologist is a surgical pathologist who is specializing in examining brain tissue or spinal cord."); *id.* at 11:21–12:2 (testifying that he did not need to consult with a neuropathologist in this case because "[w]e're not talking about brain tumors"). Dr. Iakovlev is not a neuropathologist *id.* at 10:15–18, did not consult a neuropathologist for his opinions in this case *id.* at 11:21–12:5, and has not consulted a neuropathologist in any pelvic mesh litigation about how to conduct his work *id.* at 17:24–18:6.

Dr. McLendon refutes Dr. Iakovlev's neuropathology opinions in several respects. For example, he explains how Dr. Iakovlev's opinions do not appreciate the difference between nerve fiber locations (which do not transmit pain sensations) and nerve receptor locations (which may transmit pain sensations). *See* Pls.' Motion Ex. B, McLendon Expert Report at 2. He also explains that Dr. Iakovlev failed to account for various studies and characteristics of the nerves. *Id.* at 2–3.

Dr. McLendon also explains that Dr. Iakovlev lacks a fundamental understanding of how ganglia mediate autonomic motor signals to end organs (bladder, colon, glands, blood vessels, etc.). *Id.* at 2. Most importantly, he explains that Dr. Iakovlev is simply wrong to equate the presence of small nerve twigs in proximity to mesh as proof a patient suffered pain caused by the mesh implant, particularly since Dr. Iakovlev cannot even show that these twigs contain sensory nerve fibers. *Id.* at 3.

All of these opinions lie soundly within the field of neuropathology, and Plaintiffs offer no challenge to Dr. McLendon's expertise within that field. Nor could they—Dr. McLendon is highly qualified in neuropathology, in stark contrast to Dr. Iakovlev. Dr. McLendon is a Professor of Pathology, Director of Surgical Pathology, and Chief of the Section of Neuropathology at the Duke University School of Medicine and Duke Hospital of the Duke University Health System. *See* Ex. F, McLendon CV, Ex. A to Report at 11. He has been a pathologist for over 30 years, and is a Member of the American Board of Pathology. *Id.* He has served on numerous committees in the College of American Pathologists and other national and international groups, and has approximately 300 full-length publications. *See id.* at 12-13, 18-48. In his role as a neuropathologist, Dr. McLendon's job is to examine tissues from anywhere in the body—including vaginal tissues—for nerve damage. Pls.' Motion Ex. C, McLendon Dep. Tr. 8:21–9:4.

Rather than addressing Dr. McLendon's qualifications in neuropathology, Plaintiffs offer at pages 3 and 4 of their brief a laundry list of things Dr. McLendon purportedly has not done with respect to TVT or mesh. Memorandum at 3–4. This argument wrongly assumes that mesh experience is required for Dr. McLendon's opinions.

True, Dr. McLendon has no prior research experience specific to TVT or polypropylene or mesh. But, apart from conclusory argument, Plaintiffs have made no attempt to show *why* a neuropathologist needs special experience in meshes in order to be able to opine about general

characteristics of nerves, nerve receptors, the pathogenesis of pain, the functions mediated by nerves, and the proper scientific method for studying these issues in the field of pathology or neuropathology. *See, e.g., Frankum v. Bos. Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at \*24 (S.D.W. Va. May 1, 2015) (anatomical and clinical pathologist qualified to testify about pathology of mesh material despite lack of training in polymer science or testing of mesh products). In their typical practice, neuropathologists do not have specialized training in every other medical subspecialty implicated by their work, and “[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion.” *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).

Finally, Plaintiffs selectively and misleadingly quote Dr. McLendon’s deposition in an effort to show him unqualified. For instance, Plaintiffs claim that “[a]ccording to Dr. McLendon himself, when it comes to implantable medical devices, ‘I don’t know the science. I don’t know the medicine.’” Memorandum at 1. When viewed in context, however, Dr. McLendon was not being examined about any of his actual opinions, but was being asked to speculate outside the scope of his expertise and outside the scope of his expert report:

Q. Should they have done the study [of whether scar formation causes pain] before they sold this product, Doctor? Answer the question.

...  
A: I haven’t formed an opinion on that, and I’m not going to offer one at trial. I do not develop prostheses or do any phase 1, 2 or 3 studies on implantation of prostheses. I never have done. **I don’t know the science. I don’t know the medicine. I’m not going to offer an opinion on that.**

Pls.’ Motion Ex. C, McLendon Dep. Tr. 80:20–81:5 (emphasis added).

Dr. McLendon is plainly “qualified . . . by knowledge, skill, experience, training or education” in the area of neuropathology. Fed. R. Evid. 702. All of Dr. McLendon’s opinions in this Report are clearly within the field of neuropathology, and Plaintiffs’ Memorandum offers no serious challenge to his qualifications in this area.

### **III. Dr. McLendon employs reliable methodology.**

Plaintiffs' challenge to Dr. McLendon's methodology is essentially the same as their challenge to his credentials. They argue that Dr. McLendon should be excluded because he has "performed no independent research on the transvaginal mesh and potential causes of pain." Memorandum at 5.

Again, this argument ignores the opinions and methodology actually offered by Dr. McLendon. In forming his opinions, Dr. McLendon received articles from Defendants' counsel, and he also researched articles online and consulted textbooks. Pls.' Motion Ex. C, McLendon Dep. Tr. 93:17–24.

Plaintiffs offer no challenge to the scientific authorities cited by Dr. McLendon in support of his opinions. Nor do they explain their claim that mesh-specific research is required to offer the opinions Dr. McLendon offers or why Dr. McLendon needs to know "how many studies Dr. Iakovlev has performed or how many are published" in order to critique his opinions in this case. Memorandum at 4.

Plaintiffs claim in conclusory fashion that "Dr. McLendon fails to use any true methodology at all" Memorandum at 2, but Dr. McLendon has applied the classic methodology of a neuropathologist. Dr. McLendon's methodology in examining slides and identifying the presence or absence of certain characteristics is precisely the work of a pathologist, and with respect to nerves, precisely the work of a neuropathologist. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D.W. Va. 2014) (describing "reliable pathology methods—he reviewed slides, considered the possible causes[], and came to a diagnostic conclusion").

In his Report and deposition, Dr. McLendon applied that methodology to explain in detail the shortcomings of Dr. Iakovlev's methodology and opinions. For instance, Dr. McLendon explained that pain only generates from a nerve receptor, not just from any nerve fiber. *See Pls.'*



Motion Ex. B, Expert Report of Dr. McLendon at 9–10; Pls.’ Motion Ex. C, McLendon Dep. Tr. 39:4–24. The nerve receptors do not look different from nerves on a two-dimensional slide. *Id.* at 39:9–40:8, 44:3–7. So, the method scientists generally use to determine the location of nerve receptors is to count the number of nerves on the slide and compare that to a control. *Id.* at 44:24–45:10.

When looking at a single slide, Dr. McLendon would determine whether he was looking at a nerve or a nerve receptor by staining for autonomic nerves (*i.e.*, nerves that transmit signals away from the spinal cord to the muscles, arteries, etc., and that do not relay the sensation of pain). *Id.* at 48:10–49:3. This would at least give Dr. McLendon more confidence that the nerve is a sensory nerve and not an autonomic nerve, but it still would not answer the question of whether it was a pain receptor. *Id.* at 49:17–50:6. An additional stain would need to be applied to identify a nerve receptor. *Id.* at 53:8–24.

When Dr. McLendon looked at the photographs from Dr. Iakovlev’s slides, it was impossible for him to identify any nerve receptors for two reasons. First, Dr. Iakovlev’s images were taken at too low a magnification. *Id.* at 52:4–12. A magnification of 40x–100x is required to see A delta and C fibers (which may transmit pain), and almost all of Dr. Iakovlev’s photos are 4x–20x magnification. *Id.* at 52:20–53:7. There was one photograph at 100x magnification, but it did not apply the right stain to show pain nerve receptors. *Id.* at 53:9–17. Second, Dr. Iakovlev used a stain that is appropriate for highlighting Schwann cells, which merely insulate nerve fibers; but he did not utilize the types of stains required to identify the types of nerves that can create pain (vasoactive intestinal peptide or VIP) or to identify nerve receptors (PP 9.5 or a neurofilament protein stain). *Id.* at 49:8–16, 53:19–54:16, 65:2–6.

Plaintiffs offer no critique of this methodology. Instead, Plaintiffs criticize Dr. McLendon for what he purportedly does not know or has not done. Memorandum at 3–4. But, as explained

above, this argument assumes—without any basis whatsoever—that such experience is required in the practice of neuropathology.

Further, Plaintiffs claim Dr. McLendon’s methodology is unreliable because he has not determined the cause of chronic post-operative pain syndrome and has no active research program to determine its cause. Memorandum at 5. The cause of chronic post-operative pain syndrome is the subject of significant ongoing medical research, and no expert has uncovered the cause, including Dr. Iakovlev. Pls.’ Motion Ex. C, McLendon Dep. Tr. 114:14–115:27. The fact that Dr. McLendon has not solved the puzzle confounding the scientific community at large does not preclude him from applying his neuropathological expertise to Dr. Iakovlev’s theory and concluding that Iakovlev’s theory is wrong.

Plaintiffs criticize Dr. McLendon’s testimony that it is “unknowable” if nerves that grow in or around scar tissue surrounding a properly placed TVT can cause long-term pain. Memorandum at 5 (citing Pls.’ Motion Ex. C, McLendon Dep. Tr. 23:23–24:1). But that is precisely the point—Dr. McLendon does not know the cause of long-term pain, but neither can Dr. Iakovlev know, contrary to Dr. Iakovlev’s representations. As Dr. McLendon explained, “[t]he science of it has not been analyzed, and it certainly hasn’t been done by Dr. Iakovlev’s studies or any of the studies that I’ve seen from his group” and “[t]here are a lot of other theories that do explain why people experience pain after this surgery.” Pls.’ Motion Ex. C, McLendon Dep. Tr. 24:4–14. *See also Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 834 (D. Minn. 2011) (“expert witnesses may criticize other experts’ theories and calculations without offering alternatives.”); *Smith v. Wal-Mart Stores, Inc.*, 537 F. Supp. 2d 1302, 1324–25 (N.D. Ga. 2008) (holding that expert could critique other expert’s opinion based on his specialized knowledge and experience without conducting his own tests or experiments).

Dr. McLendon’s statement that the cause of long-term pain is presently “unknowable” from a pathological perspective is not a shortcoming in Dr. McLendon’s expertise or methodology, but rather a reliable scientific opinion that directly refutes Dr. Iakovlev’s unsupported conclusions.

**IV. It is proper for an expert to criticize the methodology of another expert.**

Plaintiffs erroneously argue that Dr. McLendon should be excluded because, they say, his “sole purpose in this case is to offer a list of reasons why he believes that Dr. Iakovlev’s methods and findings are wrong.” Memorandum at 6. They cite no authority for this novel proposition because, of course, it is wrong.

First, it is inaccurate to say, as Plaintiffs have, that Dr. McLendon “is entirely unable to provide any affirmative opinions of his own.” Memorandum at 6. To the contrary, in his Report, Dr. McLendon explains the science of how pain is transmitted by the nervous system and offers his own affirmative opinions about (1) what he sees in Dr. Iakovlev’s slides and (2) the medical literature overlooked or misinterpreted by Dr. Iakovlev—in particular, the Hill article, which refutes Dr. Iakovlev’s theories about pain. *See, e.g.*, Pls.’ Motion Ex. B, Expert Report of Dr. McLendon at 2–3.

Looking past that inaccuracy, though, Plaintiffs’ argument simply misses the mark. To be sure, Dr. McLendon is critical of Dr. Iakovlev’s methodology and opinions. But it is not unusual for one expert to examine and criticize the work of another. Quite to the contrary, that is “one of the traditional roles of an expert.” *Fuji Elec. Corp. of Am. v. Fireman’s Fund Ins.*, No. 9:05CV27, 2005 WL 5960354, at \*2 (E.D. Tex. Nov. 21, 2005). Indeed, the Federal Rules specifically provide for the disclosure of rebuttal expert witness opinions “intended *solely* to contract or rebut evidence on the same subject matter identified by another party.” Fed. R. Civ. P. 26(a)(2)(D) (emphasis added). Given that the Rules specifically authorize the use of an expert

solely to rebut another expert, it is obviously wrong to argue that an expert should be excluded because he primarily criticizes another expert's methodology and opinions.

Moreover, Plaintiffs are wrong when they assert that Dr. McLendon's testimony will not assist the jury. *See* Memorandum at 6. Under Rule 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Id.* at \*1 (quoting Fed. R. Evid. 702). Dr. McLendon's testimony will help the jury understand the evidence in this case as it relates to the relationship between nerves and the sensation of pain in the human body—a point of fundamental science that is directly relevant to the theories presented in this case by Dr. Iakovlev—allowing the jury to weigh the credibility of the experts' competing theories in this case.

### CONCLUSION

For these reasons, Plaintiffs' Motion to Exclude the Opinions and Testimony of Roger McLendon, M.D. should be denied.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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